

Benjamin J Ward

From: John Fuerst <j122177@hotmail.com>
Sent: Wednesday, June 30, 2021 4:36 PM
To: Clinton F Faison; John G Fuerst
Cc: Bryan J Pesta; Kenneth B Kahn; Jianping Zhu; Sonali B Wilson; Benjamin J Ward
Subject: Re: FINAL CSU RESPONSE: NIH Data

CAUTION: This email originated from outside of Cleveland State University! Do not click links, open attachments or reply, unless you recognize the sender's email address and know the content is safe!

Guys,

I can't be done. Sunday is the earliest. I guess we are lawyering up then.

From: Clinton F Faison <c.faison@csuohio.edu>
Sent: Wednesday, June 30, 2021 8:27 PM
To: John Fuerst <j122177@hotmail.com>; John G Fuerst <j.g.fuerst@vikes.csuohio.edu>
Cc: Bryan J Pesta <b.pesta@csuohio.edu>; Kenneth B Kahn <k.b.kahn@csuohio.edu>; Jianping Zhu <j.zhu94@csuohio.edu>; Sonali B Wilson <s.b.wilson@csuohio.edu>; Benjamin J Ward <b.j.ward@csuohio.edu>
Subject: FINAL CSU RESPONSE: NIH Data

Mr. Fuerst,

I have been closely following your correspondence with Dr. Ward on this matter. I am now responding on behalf of the university. This is the university's final correspondence to you on this matter.

NIH's letter dated May 27, 2021 stated that NIH revoked data access with immediate effect, not subsequent to project close out. Further, the instructions from the NIH letter clearly stated that the data was to be destroyed immediately. The operative word for both these directives is "immediate." To this end, CSU is obligated to comply with NIH's directives. Project closeout is a separate unrelated action to be taken, now pending Dr. Pesta's appeal.

Although the data must be destroyed and removed from any and all computers, we have made arrangements and received approval from NIH to securely sequester the data under CSU access control pending the outcome of Dr. Pesta's appeal. Dr. Pesta indicated on 6/28/2021 that he was in the process of uploading data for sequestration. However, we have not yet received a signed letter from you certifying that all dbGaP data has been deleted from your computer systems and expect to receive that certification by close of business Friday, July 2, 2021. This is beyond the deadline required by NIH but represents our good faith attempt to work with you to comply with their directives. This deadline will not be extended.

Upon review of the attached documents, it is clear that both Dr. Pesta and you agreed to abide by the same sensitive data security plan. If you do not meet this deadline above, the university will be compelled to report to NIH that you are non-compliant with our request to meet their directives. Because Dr. Pesta is ultimately responsible for the data, your non-compliance with NIH directives could potentially affect NIH decisions, including Dr. Pesta's appeal, and additionally, yours and Dr. Pesta's future access to NIH data or competitiveness for NIH grants. I strongly urge you to comply with this request.

This is our final decision on this matter. I will sign out a final response to NIH at close of business on Friday, July 2, 2021.

Sincerely,

Forrest Faison

Forrest Faison, M.D., Sc.D. (hon), FAAP
Senior Vice President, Research and Innovation
Chief, Health Strategy
Cleveland State University
Cleveland, OH
c.faison@csuohio.edu

From: John Fuerst <j122177@hotmail.com>
Date: Monday, June 28, 2021 at 2:23 PM
To: Benjamin J Ward <b.j.ward@csuohio.edu>, John G Fuerst <j.g.fuerst@vikes.csuohio.edu>
Cc: Bryan J Pesta <b.pest@csuohio.edu>, Kenneth B Kahn <k.b.kahn@csuohio.edu>, Clinton F Faison <c.faison@csuohio.edu>, Jianping Zhu <j.zhu94@csuohio.edu>, Sonali B Wilson <s.b.wilson@csuohio.edu>
Subject: Re: NIH Data

CAUTION: This email originated from outside of Cleveland State University! Do not click links, open attachments or reply, unless you recognize the sender's email address and know the content is safe!

Dear Dr. Ward.

You said:

"CSU's expectation remains that the dbGaP data is to be deleted in accordance with termination and data destruction terms (copied below for reference) by today, and that Dr. Pesta will provide a signed letter certifying the data's destruction. Dr. Faison has spoken with Dr. Lauer at NIH about the data management incident, and while NIH accepts sequestering the data as an acceptable step during Dr. Pesta's appeal, they did not offer any further relief in terms of destruction of the data accessed/stored by Dr. Pesta and its derivatives (including imputed data)."

The terms clearly say, "upon Project Close-out... the Requester and Approved Users agree to destroy all copies, versions, and Data Derivatives of the dataset(s)". The term upon means "on. thereafter, therone"

As explained to NIH, neither you nor Bryan can close out now. You seem to concede the point in asking just to sequester the data (with no closeout). Forward the email from Dr. Lauer and I will directly contact him and, especially, NIH legal about this -- to get them to confirm my point. I have corresponded with them often on these technical points.

Now, you or Professor Pesta can write me up on academic insubordination, if you wish. However, if so, I will be happy to fight you both through the school bureaucracy and in court, since you are asking that I rush on no policy ground, and since doing so, as explained, will lead to errors and mostly likely NIH violations. And I am not willing to do that, since I will have to work with NIH at my new university.

I am willing to prepare this data (under Bryan supervision) -- and destroy it earlier and then close out -- and send you a copy if you want that. I take that as a personal request from CSU -- not one required by NIH for the reasons mentioned above. But it will not get done today. It will take at least a week and a half to get this done correctly.

That is a reasonable offer.

Note, I have already completed all of my analyses. The manuscripts have been accepted or already reviewed. I do not need the NIH data for any current project. So destroying that data is not a problem. However, I am not rushing this clean-up process, especially given my health.

You said, "It is not clear to me that that is consistent with the data use agreement, and in any case is not consistent Dr. Pesta's statement that the data would be contained solely on his CSU-issued device."

To be clear, we are talking about the NIMH data applied for in the summer of 2020 during the pandemic, not the Trajectories of Complex Phenotype data. I don't recall the terms. To be Frank, I don't really care. That is professor Pesta's concern.

I can prepare and get you the data by June 8th, with no further distractions.

Let me know if you agree.

JGR Fuerst
Cleveland State University
Ulster Institute for Social research

From: Benjamin J Ward <b.j.ward@csuohio.edu>
Sent: Monday, June 28, 2021 1:03 PM
To: John G Fuerst <j.g.fuerst@vikes.csuohio.edu>
Cc: Bryan J Pesta <b.pest@csuohio.edu>; Kenneth B Kahn <k.b.kahn@csuohio.edu>; Clinton F Faison <c.faison@csuohio.edu>; Jianping Zhu <j.zhu94@csuohio.edu>; Sonali B Wilson <s.b.wilson@csuohio.edu>
Subject: RE: NIH Data

Mr. Fuerst,

CSU's expectation remains that the dbGaP data is to be deleted in accordance with termination and data destruction terms (copied below for reference) by today, and that Dr. Pesta will provide a signed letter certifying the data's destruction. Dr. Faison has spoken with Dr. Lauer at NIH about the data management incident, and while NIH accepts sequestering the data as an acceptable step during Dr. Pesta's appeal, they did not offer any further relief in terms of destruction of the data accessed/stored by Dr. Pesta and its derivatives (including imputed data).

You state in your email "That data is encrypted on a password-protected desktop which is under Dr. Pesta's guardianship, consistent with the NIMH contract." It is not clear to me that that is consistent with the data use agreement, and in any case is not consistent Dr. Pesta's statement that the data would be contained solely on his CSU-issued device.

13. Termination and Data Destruction

Upon Project Close-out, the Requester and Approved Users agree to destroy all copies, versions, and Data Derivatives of the dataset(s) retrieved from NIH-designated controlled-access databases, on both local servers and hardware, and if cloud computing was used, delete the data and cloud images from cloud computing provider storage, virtual and physical machines, databases, and random access archives, in accord with the NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy. However, the Requester may retain these data as necessary to comply with any institutional policies (e.g., scientific data retention policy), law, and scientific transparency expectations for disseminated research results,

and/or journal policies. A Requester who retains data for any of these purposes continues to be a steward of the data and is responsible for the management of the retained data in accordance with the NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy, and any institutional policies. Any retained data may only be used by the PI and Requester to support the findings (e.g., validation) resulting from the research described in the DAR that was submitted by the Requester and approved by NIH. The data may not be used to answer any additional research questions, even if they are within the scope of the approved Data Access Request, unless the Requester submits a new DAR and is approved by NIH to conduct the additional research. If a Requester retains data for any of these purposes, the relevant portions of Terms 4, 5, 6, 7, 8, and 12 remain in effect after termination of this Data Use Certification Agreement. These terms remain in effect until the data is destroyed.

Regards,

Benjamin J. Ward, PhD
Director, Research Development
Office of Research
Cleveland State University
E: b.j.ward@csuohio.edu
P: 216-687-4536
Please support research and innovation at CSU: <https://www.csuohio.edu/support-research>

From: John G Fuerst <j.g.fuerst@vikes.csuohio.edu>
Sent: Monday, June 28, 2021 6:06 AM
To: Benjamin J Ward <b.j.ward@csuohio.edu>
Cc: Bryan J Pesta <b.pest@csuohio.edu>
Subject: Fwd: NIH Data

Dear Dr. Ward,

This is John Fuerst. I am a student/research assistant of Bryan Pesta. Bryan applied for the dbgap data to facilitate my (class) research projects. I am doing these projects for research experience. My graduate field of study was experimental psychology, but I am now seeking an MS in bioinformatics.

Bryan forwarded your request as I largely write the code, design the analyses and run them under his supervision.

That data is encrypted on a password-protected desktop which is under Dr. Pesta's guardianship, consistent with the NIMH contract. It is disconnected from the internet and so not going anywhere.

I have agreed to begin preparing the data for CSU. I will go over Monday afternoon (3pm). However, as I notified NIH, this will take time since we have to sort through thousands of files. The data is mixed with 1000 Genomes and Hapmap data, pipelines, notebook files, etc.

I need to separate out raw and derived data, so I can just plug in new data, which I arranged for elsewhere following a similar arrangement to the one I had with Bryan. Unfortunately, I have a clinically diagnosed mitochondrial disorder, hence I work at partial speed, which is why I have been rather slow with the research, too. So you will have to be patient!

However, I will make sure that our school does not fall in non-compliance with the NIH contract. I do not think we have, yet!

You and Dr. Kahn have expressed concerns about NIH's request to CSU, which you have interpreted to mean that the data must be destroyed as of yesterday:

"I have shared your emails with CSU's VP of Research Office. They are still obligated to respond to NIH by June 27 and adhere to their given instructions. Hence, IS&T will need to store the dbGaP data and derivatives for the duration of your appeal to NIH."

"NIH's letter dated May 27 was directed to CSU, and we are obliged to comply with NIH's instructions. Your appeal to NIH is a separate matter, so we are providing the accommodation of secure storage of the data accessed and its derivatives during the appeal."

You are misreading the request, I believe. I wrote for clarification from NIH about the timeline for destroying the data given the circumstances. And notified them about the timeframe.

There are complex rules for handling the data. I do not plan to fall in non-compliance with NIH by rushing this.

Thank you for your support.

Sincerely,
JGR Fuerst

-----Original Message-----

From: Bryan J Pesta <b.pest@csuohio.edu>

To: Bryan Pesta <bpest22@cs.com>

Sent: Sun, Jun 27, 2021 2:04 am

Subject: Fw: NIH Data

From: Benjamin J Ward <b.j.ward@csuohio.edu>

Sent: Saturday, June 26, 2021 11:54 PM

To: Bryan J Pesta <b.pest@csuohio.edu>; Kenneth B Kahn <k.b.kahn@csuohio.edu>

Cc: Clinton F Faison <c.faison@csuohio.edu>; Sonali B Wilson <s.b.wilson@csuohio.edu>; Jianping Zhu <j.zhu94@csuohio.edu>; Justin D Grogan-Myers <j.d.myers29@csuohio.edu>

Subject: RE: NIH Data

Dr. Pesta,

It is understood that you have teaching obligations to attend to this weekend. We expect that you will make the data transfer a priority and send us a signed letter certifying that the dbGaP data/data derivatives have been uploaded to the secure drive and deleted from your computer system(s) no later than COB Monday.

Please consult with Justin Grogan-Myers if there are any issues with transferring the dbGaP data/data derivatives.

Regards,

Ben